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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,170	06/26/2003	Cathy Klech Gelotte	MCP 275 CON 2	8241

27777 7590 11/01/2004

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,170	GELOTTE ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment received 26 June 2003 has been entered and claims 18-42 are currently pending in this application.

Response to Amendment

Objection of the specification, correcting the cross-reference information is no longer maintained in view of the amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Sunshine et al. U.S. Patent No. 4,783,465.

The claim is drawn to a stable suspension comprising a pharmacologically effective amount of a pharmaceutically effective amine and a pharmacologically effective amount of a pharmaceutically effective non-steroidal anti-inflammatory drug.

Sunshine et al. teach a pharmaceutical composition comprising an NSAID combined with a non-sedating antihistamine and optionally one or more active components such as decongestants (amines) (see abstract). The composition are

administered in admixtures in the form of *inter alia* suspensions (column 12, lines 50-58).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. U.S. Patent No. B1 4,552,899.

Claims 28-41 are drawn to a stable suspension comprising pharmacologically effective amounts of an amine and a pharmacologically effective amount of a non-steroidal anti-inflammatory drug (NSAID). Dependent claims are drawn to ibuprofen and pseudoephedrine and to specific dosages of ibuprofen/pseudoephedrine.

Sunshine et al. combines NSAID's such as ibuprofen in doses of from 50 to 400mg or in general, propionic acid derivatives in doses of from 25 mg to about 600 mg (column 4, lines 27) with pseudoephedrine (column 6, lines 61-67) for use as a preserved syrup formulation (column 12-13, lines 50-9). See also claims 21-23, 25, 26, 28 and especially claim 36. The composition is administered in admixture with suitable pharmaceutical diluents, excipients or carriers suitably selected with respect to the intended form of administration, i.e., oral tablets, capsules, elixirs, syrups, etc. (column 5, line 50 to column 6, line 61).

It does not specifically recite a suspension. However it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a suspension base motivated by the well-known teaching that ibuprofen is not soluble in water, and as such, the ibuprofen would necessarily be suspended in the syrup aforementioned.

Regarding the dosages, Sunshine et al. teach ibuprofen doses ranging from 25 mg to 400 mg and propionic acid derivatives ranging from 25 to 600 mg. Although the amount recited in, for example, instant claim 25 is not encompassed by the doses of the patent, as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude, for instance, treatment of an adult vs. treatment of a child, or a patient having an unusually severe pain would require a correspondingly higher dosage of ibuprofen. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. For these and other self-evident reasons, it would have been obvious to have used higher dosages of ibuprofen. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the **dosage regimen** desired for the composition.

Non-Statutory Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,211,246 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are drawn to a a method for enhancing the absorption rate of an amine comprising administering a **stable liquid form** of the composition comprising an amine (such as pseudoephedrine) and a NSAID (such as ibuprofen). The claims of the instant application are drawn to a **suspension**. Since a stable liquid form is inclusive of a suspension, it would have been obvious to incorporate the composition of the patent into a suspension, since it is well known that ibuprofen is not a water soluble drug and must necessarily be suspended when in a liquid form.

Claims 29-41 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-30 of U.S. Patent No. 6,211,246 B1.

The claims are drawn to a stable liquid suspension. The claims of the patent are drawn to a stable liquid composition. It differs in that the claims of the patent are drawn to stable liquid composition with dependent claims to a suspension. It would have been obvious to compound an ibuprofen/pseudoephedrine liquid into a suspension since

ibuprofen is not a water-soluble drug and as such must necessarily be suspended in when in liquid form.

Claim 42 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,211,246 B1.

The claim is drawn to the suspension of claim 30 wherein the suspension further comprises xanthan gum, pregelatinized starch, polyoxyethylene sorbitan monooleate and a taste masking agent selected from sugar, sweet polyhydric alcohol, cyclamates, aspartame, sucralose, saccharin, flavoring agents and mixtures thereof.

Claim 14 of the patent is drawn to a composition comprising a pharmacologically effective amount of amine and a pharmacologically effective amount of a NSAID wherein the amine and the NSAID are in a stable liquid suspension and further comprise all the elements of instant claim 42. The claims are the same when the limitations of claims 20 and 28 are taken into consideration, from which instant claim 42 depends.

Claim 42 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and with a timely filed terminal disclaimer as indicated above.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday and Thursday from 9:00 A.M. - 7:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe
Patent Examiner
Art Unit 1614

10/20/2004

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